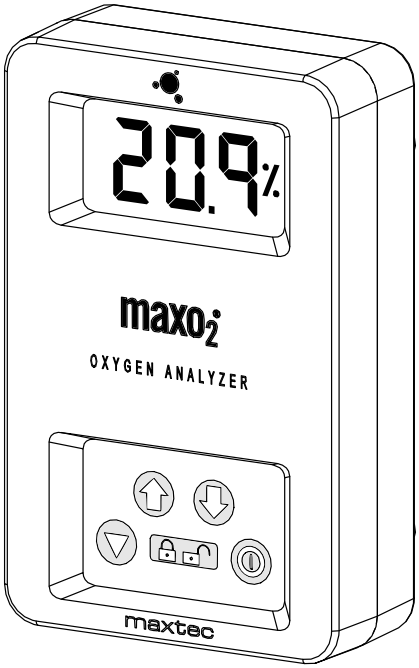

MaxO2®

OPERATING MANUAL & INSTRUCTIONS FOR USE

OM-25A

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This manual describes the function, operation and maintenance of the Maxtec Model OM-25A hand-held oxygen analyzer. A member of Maxtec's $MAXO_2$® analyzer line of oxygen analyzers and monitors, the OM-25A utilizes the MAX-250 oxygen sensor and is engineered for fast response, maximum reliability and stable performance. The OM-25A is designed primarily for spot-checking oxygen concentration delivered by oxygen concentrator units, however, its internal sensor and adaptable sampling port make it suitable for a wide variety of oxygen analysis applications.

CLASSIFICATION

Classification: . . . . . .Class II medical device.
Protection against electric shock:. . . . . Internally powered equipment.
Protection against water: . . . . . Ordinary Equipment
Mode of Operation:. . . . . Continuous
Sterilization: . . . . . See section 6.0
Safety of application in the presence of a flammable anesthetic mixture: . . . . .See Section 8.1

Product Disposal Instructions:
The sensor, batteries, and circuit board are not suitable for regular trash disposal. Return sensor to Maxtec for proper disposal or dispose according to local guidelines. Follow local guidelines for disposal of other components

WARRANTY

The $MAXO_2$® Analyzer is designed for medical oxygen delivery equipment and systems. Under normal operating conditions, Maxtec warrants the $MAXO_2$® Analyzer to be free from defects of workmanship or materials for a period of two (2) years from the date of shipment from Maxtec, provided that the unit is properly operated and maintained in accordance with Maxtec's operating instructions. Based on Maxtec's product evaluation, Maxtec's sole obligation under the foregoing warranty is limited to making replacements, repairs, or issuing credit for equipment found to be defective. This warranty extends only to the buyer purchasing the equipment directly from Maxtec or through Maxtec's designated distributors and agents as new equipment. Maxtec warrants the MAX-250 oxygen sensor in the $MAXO_2$® Analyzer to be free from defects in material and workmanship for a period of two (2) years from Maxtec's date of shipment in a $MAXO_2$® unit. Should a sensor fail prematurely, the replacement sensor is warranted for the remainder of the original sensor warranty period. Routine maintenance items, such as batteries, are excluded from warranty. Maxtec and any other subsidiaries shall not be liable to the purchaser or other persons for incidental or consequential damages or equipment that has been subject to abuse, misuse, mis-application, alteration, negligence or accident. THESE WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NOTE: In order to obtain optimum performance from your MAXO$_2$® analyzer, all operation and maintenance must be performed in accordance with this manual. Please read the manual thoroughly before using the analyzer and do not attempt any repair or procedure that is not described herein. Maxtec cannot warrant any damage resulting from misuse, unauthorized repair or improper maintenance of the instrument.

WARNINGS ⚠

FAILURE TO COMPLY WITH THESE WARNINGS AND CAUTIONS COULD RESULT IN INSTRUMENT DAMAGE AND POSSIBLY JEOPARDIZE THE WELL BEING OF THE PATIENT AND/OR HEALTH CARE PROFESSIONAL.

- The sensor of the MAXO$_2$ Oxygen Analyzer (MAXO2) has been tested with various anesthesia gases including Nitrous oxide, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane and found to have acceptable low interferance, the device in its entirety (including electronics) is not suitable for use in the presense of a flammable anesthetic mixture. Only the threaded sensor face and sample inlet connection may be allowed to contact such a gas mixture.
- To avoid explosion, do not operate the oxygen analyzer in the presence of flammable anesthetics or in an atmosphere of explosive gases. Operating the oxygen analyzer in flammable or explosive atmospheres may result in fire or explosion.
- Never allow an excess length tubing near the patient's head or neck, as such could result in strangulation.
- Before use, all individuals who will be using the MAXO$_2$ must become thoroughly familiar with the information contained in this Operation Manual. Strict adherance to the operating instructions is necessary for safe effective product performance. This product will perform only as designed if installed and operated in accordance with the manufacturer's operating instructions.
- Use only genuine Maxtec accessories and replacement parts. Failure to do so may seriously impair the monitor's performance. Repair or alteration of the MAXO$_2$ beyond the scope of the maintenance instructions or by anyone other than an authorized Maxtec service person could cause the product to fail to perform as designed.
- Calibrate the MAXO$_2$ weekly when in operation and if enviromental conditions change significantly. (ie, Temperature, Humidity, Barometric Pressure. --- Refer to Calibration section of this manual).
- Use of the MAXO$_2$ near devices that generate electrical fields may cause erratic readings.
- If the MAXO$_2$ is ever exposed to liquids (from spills or immersion) or to any other physical abuse, turn the instrument OFF and then ON. This will allow the unit to go through its self test and make sure everything is operating correctly.
- Never autoclave, immerse or expose the MAXO$_2$ (including sensor) to high temperatures (>70˚C). Never expose the device to pressure, irradiation vacuum, steam, or chemicals.
- To protect the unit from potential leaky battery damage always remove batteries when the unit is going to be stored (not in use for 1 month) and replace dead batteries with recognized name brand AA Alkaline batteries. **Do not use rechargeable batteries.**
- This device does not contain automatic barometric pressure compensation.
- Not for use in an MRI environment.

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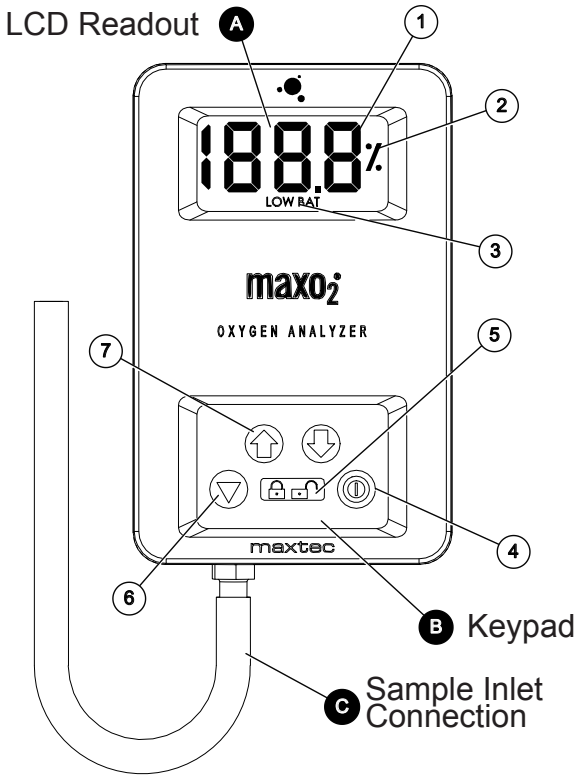
Symbol Guide

The following symbols and safety labels are found on the $MAXO_2$®:

Attention, consult accompanying documents	REF Catalog Number
Meets ETL standards	SN Serial Number
Do not throw away. Follow local guidelines for disposal.	LOW BAT Low Battery
LOT Lot code/Batch code	RXonly Use by prescription only
Manufacturer	EC REP Authorized Representative in the European Community

Component Diagram



OM-25A

1.0 SYSTEM OVERVIEW

1.1 Base Unit Description

The $MAXO_2$® analyzer (Model OM-25A) provides unparalleled performance and reliability, due to an advanced design that includes the following features and operational benefits.

» Fast-responding, oxygen-specific, galvanic sensor that achieves 90% of final value in approximately 15 seconds at room temperature.
» Extra-life oxygen sensor of approximately 1,500,000 O2 percent hours (minimum 2 years in most applications).
» Adaptable sample input connection and internal sensor.
» Operation using 2 AA alkaline batteries (2 x 1.5 volts) for approximately 3000 hours of performance in typical usage. For extra extended long life, 2 AA lithium batteries may be used.
» Durable, compact case that permits comfortable, hand-held operation.
» Large, easy-to-read, 3 1/2-digit LCD display for readings in the 0-100% range.
» Simple operation and calibration using quick-calibrate key functions.
» Self-diagnostic check of analog and microprocessor circuitry.
» Low battery indication.

1.2 Components Description (please refer to page IV)

A LCD Readout

1. **3 1/2-Digit Display-** The 3 1/2-digit liquid crystal display (LCD) provides direct readout of oxygen concentrations in the range of 0-100%. It also displays "CAL" when the calibration mode is entered.

2. **"%" Sign-** The percent sign indicates when the unit is locked or unlocked and when the unit is calibrating.

3. **Low Battery Indicator-** The low battery indicator appears on the LCD display when the power supply voltage drops below acceptable limits. When the "LOW BAT" icon is visible, batteries should be replaced immediately.

B Keypad

4. **ON/OFF Key-** This key is used to turn the instrument on or off.

5. **LOCK/UNLOCK Key-** The presence of the "%" sign on the LCD readout is an indication that the unit is in its normal "LOCKED" state. Pressing the LOCK key will unlock the keypad and cause the "%" sign to disappear. If no other keys are pressed within 10 seconds, the "%" sign will reappear and the unit will revert to the "LOCKED" mode.

6. **CALIBRATE Key-** When the keypad is unlocked, the CAL key is used in conjunction with the up and down keys to calibrate the device.

⑦ **and** **Keys-** The up and down arrow keys are used in conjunction with the CALIBRATE key to calibrate the device.

Ⓒ **Sample Inlet Connection**

1.3 MAX-250 Oxygen Sensor

MAX-250 oxygen sensors offer quick response, stability and extra life on the order of 1,500,000 percent hours.

The MAX-250 is a galvanic, partial pressure sensor that is specific to oxygen. It consists of two electrodes (a cathode and an anode), a teflon membrane and an electrolyte. Oxygen diffuses through the teflon membrane and immediately reacts electrochemically at a gold cathode. Concurrently, oxidation occurs electrochemically at a lead anode, generating an electrical current and providing a voltage output. Electrodes are immersed in a unique gelled weak acid electrolyte which is responsible for the sensors long life and motion insensitive characteristic. Since the sensor is specific to oxygen, the current generated is proportional to the amount of oxygen present in the sample gas. When no oxygen is present, there is no electrochemical reaction and therefore, negligible current is produced. In this sense, the sensor is self-zeroing.

CAUTION: The Maxtec MAX-250 oxygen sensor is a sealed device containing a mild acid electrolyte, lead (Pb), and lead acetate. Lead and lead acetate are hazardous waste constituents and should be disposed of properly, or returned to Maxtec for proper disposal or recovery.

CAUTION: Do not use ethylene oxide for sterilization. Do not immerse the sensor in any cleaning solution, autoclave or expose the sensor to high temperatures.

CAUTION: Dropping or severely jarring the sensor after calibration may shift the calibration point enough to require recalibration.

2.0 SET-UP PROCEDURE

2.1 Battery Installation

All $MAXO_2$® analyzer units are powered by two, AA alkaline batteries (2 x 1.5 Volts) and are shipped without the batteries installed. The battery compartment is accessible from the back side of the unit. To install the batteries:

1. With the thumb, press down on the center of the battery compartment cover and slide the cover off of the instrument case.
2. Install the two, AA, alkaline batteries (2 x 1.5 Volts) in the unit, observing the orientation shown on the label inside the compartment.

3. Slide the battery compartment cover back onto the case. Make sure the tabs on the cover snap into position, securing the cover flush against the case.

When batteries are installed in the $MAXO_2$® analyzer, the unit initiates a self-diagnostic test. All segments of the LCD readout are turned on for approximately 2 seconds. When the diagnostic test is completed successfully, the word "CAL" will appear on the display, indicating that the unit is ready to be calibrated.

2.2 Calibrating the $MAXO_2$® Analyzer

2.2.1 Before You Begin

The $MAXO_2$® Oxygen Analyzer should be calibrated upon receipt. Thereafter, Maxtec recommends calibration on a weekly basis. However, more frequent calibration will not adversely affect product performance. More frequent calibration is required when:

» The temperature of the gas stream changes by more than 3 degrees Celsius.

» Changes in elevation result in calibration error of approximately 1% of reading per 250 feet. In general calibration of the instrument should be performed when the geographic elevation at which the product is being used changes by more than 500 feet.

In addition, calibration is recommended if the user is unsure when the last calibration procedure was performed or if the measurement value displayed is in question.

It is best to calibrate the $MAXO_2$® analyzer to a known documented oxygen concentration at a pressure and flow similar to your clinical application. Calibrating the $MAXO_2$® analyzer at lower concentrations with a known oxygen value is also acceptable and may provide additional accuracy if the calibration gas is closer to the environment in which the $MAXO_2$® analyzer will be used. A “known” value of oxygen is defined as an oxygen source which has a traceable certificate and / or USP certification.

Note: Before beginning calibration the MAX-250 sensor must be in thermal equilibrium. You may also need to be aware of other factors which affect device calibration values. For more information, refer to “Factors Influencing Calibration”, section 2.2.4 in this manual.

2.2.2 To Calibrate the $MAXO_2$® Analyzer

1. Connect the sample hose to the barbed fitting on the bottom of the unit.
2. Attach the other end of the sample hose to the source of the known oxygen concentration and initiate flow of the calibration

gas to the unit at a rate of 1-10 liters per minute(2 liters per min. is recommended).

3. Using the ON/OFF key , make sure the unit is in the power on mode.
4. Allow the oxygen reading to stabilize. This will normally take about 30 seconds or more.
5. Press the LOCK/UNLOCK key to unlock the keypad. “UL” will appear on the display for about 1 second and then the "%" sign will disappear from the display.
6. Press the CALIBRATE key on the keypad. The word "CAL" will appear on the display for about 1 second and then the "%" sign will start to flash.
7. Use the and arrow keys to adjust the displayed oxygen concentration to the level of the known concentration. Pressing the arrow keys changes the value in .1% increments. If the keys are held down for more than 1 second the display will scroll at a rate of .4% per second.

   Note: If 10 seconds elapse between key actuations, the system will store the latest calibration value and will revert to normal operation. If this occurs inadvertently, simply repeat the calibration procedure.

8. When the calibration value is set, press the CALIBRATE or LOCK/UNLOCK key again to accept the calibration setting and return to normal operation.

   Note: If the message "CAL," followed by the message "Er" flashes on the display after entering the desired calibration value, the system has determined that the entered value will not allow operation within the specified output range of the sensor. This situation may occur if:

   a) the operator has inadvertently entered the wrong concentration for the calibration gas.

   b) the concentration of the calibration gas is not correct.

   c) the sensor is in need of replacement.

   d) the operator attempted to adjust the monitor before allowing sufficient time for the calibration gas to purge out the previous sample.

   e) the flow and pressure of the calibration gas was not properly regulated.

   Check these items and repeat calibration. If calibration error

continues to occur, contact the service department of the distributor from which the unit was purchased, or you may call Maxtec's Customer Service Department directly.

2.2.3 Automatic Calibration to Room Air

The $MAXO_2$® analyzer can quickly be calibrated to room air (20.9%) using a quick-key shortcut command. This function saves time by setting the calibration value to 20.9% without scrolling the display. To use this function:

1. Introduce room air to the sensor at a rate of 1-5 liters per minute (2 liters per minute is recommended) and allow the reading to stabilize.
2. Press the LOCK/UNLOCK key to unlock the keypad.
3. Press and **hold down** the CALIBRATE key . When the "%" sign starts to flash, press the arrow key to set the calibration value to 20.9%.
4. Release **both** the CALIBRATE key and the key.

The unit will automatically enter the “LOCKED” condition and return to normal operation.

2.2.4 Factors Influencing Calibration

The primary factors influencing the $MAXO_2$® analyzer are temperature, pressure, and humidity.

Effects of Temperature

The $MAXO_2$® analyzer will hold calibration and read correctly within +/- 3% when in thermal equilibrium within the operating temperature range. The device must be thermally stable when calibrated and allowed to thermally stabilize after experiencing temperature changes before readings are accurate. For these reasons, the following is recommended:

1. Allow adequate time for the sensor to equilibrate to a new ambient temperature.
2. For best results, perform the calibration procedure at a temperature close to the temperature where analysis will occur.

Pressure Effect

Readings from the $MAXO_2$® analyzer are proportional to the partial pressure of oxygen. The partial pressure of Oxygen (PO_2) is equal to the percentage of oxygen ($\%O_2$) times the absolute pressure (AP) at which the sample enviroment is measured. ($PO_2=\%O_2$ x AP). Thus the readings are proportional to the concentration if the pressure is held constant. Flow rate of sample gas can affect pressure at the

sensor in that back pressure at the sensing point may change. For these reasons, the following is recommended:

1. Calibrate the $MAXO_2$® analyzer at the same pressure as the sample gas.
2. If sample gases flow through tubing, use the same apparatus and flow rates when calibrating as when measuring.
3. The $MAXO_2$® analyzer oxygen sensor has been validated at pressures up to 2 atmospheres absolute. Calibration or operation above this pressure is beyond the intended use.

Humidity Effect

Humidity has no effect on the performance of the $MAXO_2$® analyzer other than diluting the gas, as long as there is no condensation. Depending on the humidity, the gas may be diluted by as much as 4%, which proportionally reduces the oxygen concentration from the dry concentration. Environments where condensation may occur are to be avoided since condensate may obstruct passage of gas to the sensing surface, resulting in erroneous readings and slower response time. For this reason avoid usage in environments greater than 95% relative humidity.

3.0 OPERATING INSTRUCTIONS

To check the oxygen concentration of a sample gas: (after the unit has been calibrated)

1. Connect the sample hose to the barbed fitting on the bottom of the unit.
2. Attach the other end of the sample hose to the sample gas source and initiate flow of the sample to the unit at a rate of 1-5 liters per minute (2 liters per minute is recommended).
3. Using the ON/OFF key ⏻, make sure the unit is in the power on mode.
4. Allow the oxygen reading to stabilize. This will normally take about 30 seconds or more.

4.0 SENSOR REMOVAL AND REPLACEMENT

The OM-25A is shipped with a new MAX-250 oxygen sensor installed. Although the sensor has a very long expected life, eventually the sensor will require replacement. Removing or installing a sensor, when necessary, is a very simple procedure. To remove and install a new sensor:

1. With the front of the analyzer facing downward and the bottom facing away from you, press down with both thumbs on the center of the battery compartment cover and slide the cover off.

2. Remove the white barb fitting by turning the barb counter-clockwise. A 7/16” wrench may be needed to aid in the removal.
3. Remove the expired sensor from the sensor compartment and carefully pull apart the small white connector that connects the black and red sensor wires to the analog input wiring.

Note: The sensor contains lead and lead acetate, be sure to dispose of expired sensors in accordance with hospital, local, state and federal regulations.

4. Remove the new sensor from the packaging and remove the protective film from the sensor face.
5. Attach the new MAX-250 sensor connector to the $MAXO_2$® analyzer input connector. The connector halves are keyed for proper orientation.
6. Position the sensor in the sensor compartment with the threaded end of the sensor toward the bottom of the unit and the red and black wires in the upward position, with the connectors tucked in the compartment space on the right.
7. Replace the barb fitting in the bottom of the case by turning the barb clockwise with a 7/16” wrench. The barb fitting needs to be tightened firmly against the bottom of the sensor.
8. Slide the battery compartment cover back onto the case. Make sure the tabs on the cover snap into position.
9. Wait approximately 20 minutes for the sensor to reach equilibrium.
10. Calibrate the new sensor.

NOTE: If the analyzer is on when the sensor is detached and replaced, the analyzer will automatically force a re-calibration. The display will read “CAL”.

5.0 PROBLEM SOLVING

» If the "LOW BAT" icon is displayed on the LCD readout at any time, the batteries should be replaced as soon as possible.

» When the unit is in the power on mode and the LCD displays "000%," the sensor is not connected properly. Check the sensor connection and if the condition persists, contact Maxtec Customer Service.

» If, at any time, "ErX" (i.e. Er1, Er4, etc.) appears on the LCD readout, contact Maxtec's Customer Service Department.

6.0 CLEANING AND MAINTENANCE

» When cleaning or disinfecting the $MAXO_2$® analyzer, take appropriate care to prevent any solution from entering the instrument.

» The $MAXO_2$® analyzer’s surface may be cleaned using a mild detergent and a moist cloth.

» The $MAXO_2$® analyzer may be disinfected using standard topical disinfectants.

» The $MAXO_2$® analyzer is not intended for steam, ethylene oxide or radiation sterilization.

» Store the $MAXO_2$® analyzer in a temperature similar to its ambient environment of daily use.

7.0 SPECIFICATIONS

7.1 Base Unit Specifications

Measurement Range: 0.0-100%
Resolution: 0.1%
Accuracy and Linearity: . . . . . ±1% of full scale at constant temperature, R.H. and pressure when calibrated at full scale
Total Accuracy: . . . . . ±3% Actual Oxygen Level over full operating temperature range
Response Time: . . . . . 90% of final value in approximately 15 seconds at 23°C
Warm-up Time: . . . . . none required
Operating Temperature: . . . . . 15°C - 40°C (59°F - 104°F)
Storage Temperature: . . . . . -15°C - 50°C (5°F - 122°F)
Atmospheric Pressure: . . . . . 800-1013 mBars
Humidity: . . . . . 0-95% (non-condensing)
Power Requirements: . . . . . 2, AA Alkaline batteries (2 X 1.5 Volts)
Battery Life: . . . . . approximately 3000 hours in typical use
Low Battery Indication: . . . . . "LOW BAT" icon displayed on LCD
Sensor Type: . . . . . Maxtec MAX-250 galvanic fuel cell
Expected Sensor Life: . . . . . >1,500,000% O_2 Hours, over 2 years in typical applications
Dimensions: . . . . . 3.5"(W) x 5.5"(H) x 1.5"(D) [89mm x 140mm x 38mm]
Weight: . . . . . approximately .92 lbs. (417g)

7.2 Sensor Specifications

Type: . . . . . galvanic fuel sensor (0-100%)
Life: . . . . . 2 years in typical applications

Interferent	Volume % Dry	Interference in O2%
Nitrous Oxide	75%	<2%
Carbon Dioxide	10%	<2%
Halothane	5%	<2%
Enflurane	5%	<2%
Isoflurane	5%	<2%
Helium	70%	<2%
Sevoflurane	6%	<2%
Desflurane	15%	<2%

8.0 APPLICATIONS

8.1 Exposure to Anesthetic Gases

Because of the unique chemistry of the oxygen sensors provided with the $MAXO_2$® analyzer, there are no significant effects when exposed to commonly used anesthetic gases, however, the analyzer is not designed for exposure to flammable gas mixtures. (See WARNING page ii)

8.2 Calibration Techniques in Pressurized Systems

Similar to other oxygen sensors, the MAX series sensors measure the partial pressure of oxygen in a gas stream. This is correlated to read "percent oxygen" on the $MAXO_2$® analyzer. It is important to note that the sensor output is directly proportional to the pressure of oxygen. Thus, one must take into consideration the effect of exposing the sensor to various gas sample pressures.

For example, if an analyzer is calibrated to read 20.9% in ambient air (atmospheric pressure) and then exposed to a pressurized gas sample containing a known concentration of oxygen, the analyzer will display a reading greater than the actual oxygen percentage. This is because the analyzer was originally calibrated at atmospheric pressure (0 psig) then exposed to a higher pressure sample (eg, 5 psig). The greater the difference in pressure, the greater the difference in sensor signal (oxygen reading on the analyzer).

By the same token, if an analyzer is calibrated on a pressurized gas sample containing a known concentration of oxygen and then exposed to ambient air (atmospheric pressure), the analyzer will display a reading less than the actual oxygen percentage.

To avoid confusion, the analyzer can be calibrated at a single point on a gas stream similar to the application. If, for example, the purpose of the analyzer is to measure oxygen in a concentrator or anesthesia application, the optimal results may be attained by calibrating the instrument on a gas of similar concentration and pressure. This would typically be done by connecting to a cylinder of a known high concentration of oxygen calibration gas and adjusting the flow and pressure to match the application before calibrating the instrument.

8.3 Calibration Errors

The $MAXO_2$® analyzers have a self test feature built into the software to detect faulty calibrations. During calibration, if the signal from the oxygen sensor is outside the limits stored within the instrument's memory, a flashing "CAL Er" is displayed. The error code is displayed to indicate that either the sensor should be replaced or that there is a fault in the calibration process. A few simple hints can prevent calibration errors.

If you try to adjust the analyzer display before the reading has stabilized,

the “CAL Er” may appear. For example, if the analyzer had just been calibrated on a known high concentration of oxygen source gas and then exposed to ambient air, you should wait until the reading has stabilized. If you try to adjust the display to read 20.9% before the sample line has cleared of high concentration O2, the sensor may actually be exposed to residual high % oxygen. The signal from the sensor would still be high and considered “out of spec” for air, thus resulting in a “CAL Er”. The proper procedure is to wait for the reading to stabilize before adjusting the display. This may take 30 seconds or more.

8.4 Atmospheres of High Humidity

The $MAXO_2$® analyzer can be used in applications where the relative humidity of the sample gas ranges from 0 to 95%, non-condensing. However, it should be noted that water vapor exerts its own pressure in the same manner as oxygen does in a sample gas stream.

For example, if the $MAXO_2$® analyzer is calibrated in dry gas and then the gas is humidified, the analyzer will correctly display a reading which is slightly lower than previously displayed. This is due to the dilution of oxygen in the sample gas by water vapor.

Gas streams of high humidity may tend to condense on the sensor. Condensation on the sensor may eventually affect performance. For this reason, it is recommended that the unit be used in a vertical position, with the barb fitting pointing downward to prevent condensate from flowing onto the sensing surface.

9.0 SPARE PARTS AND ACCESSORIES

Part Number	Item
R125P01-002	MAX-250 Internal Sensor
R212P91	Battery Cover
R212P17	Keypad
R212P10	LCD Display
R212P30-002	PCBA Board
Accessories	
R213P02	Monitor/Analyzer Protective Carrying Case
R213M15	OM-25A Operating Instructions
R213M66	Technical Service Manual

Although normal usage will not require repair, Maxtec will make available, on request, diagrams, descriptions and instructions to assist user’s appropriately qualified technical personnel in repairing and replacing broken or worn components.